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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/721,506	11/22/2000	Thomas R. Cech	015389-002610	5211
34151	7590	11/18/2003	EXAMINER	
TOWNSEND AND TOWNSEND AND CREW LLP			SISSON, BRADLEY L	
8TH FLOOR			ART UNIT	
TWO EMBARCADERO CENTER			PAPER NUMBER	
SAN FRANCISCO, CA 94111			1634	

DATE MAILED: 11/18/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Applicati n No.	Applicant(s)	
	09/721,506	CECH ET AL.	
	Examin r	Art Unit	
	Bradley L. Sisson	1634	

-- The MAILING DATE of this communication appears on the cov r sh et with th correspond nce addr ss --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 November 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 73-104 is/are pending in the application.
- 4a) Of the above claim(s) 73,74,79-82,87-90 and 95-100 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 75-78,83-86 and 91-94 is/are rejected.
- 7) ☒ Claim(s) 75-78,83-86,91-94 and 101-104 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group II, claims 75-78, 83-86, 91-94, and 101-104, in the response received 06 November 2003 is acknowledged.
2. Claims 73, 74, 79-82, 87-90, and 95-100 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the response of 06 November 2003.

Response to Amendment

3. Acknowledgement is made of the cancellation of all previous claims, claims 1-72, and the addition of claims 73-104 via the amendment of 06 November 2003.

Claim Objections

4. Claims 101-104 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from more than one claim at the same time. In the instant case claims 101-104 depend from claim 75 as well as from claim 97, 98, 99, or 100, respectively. See MPEP § 608.01(n). Accordingly, the claims 101-104 have not been further treated on the merits.
5. Claims 75-78, 83-86, and 91-94 are objected to because of the following informalities: Claims depend from claim 73; claims 83-86 depend from claim 81; and claims 91-94 depend

Art Unit: 1634

from claim 89. Said claims 73, 81, and 89 have been withdrawn from consideration without traverse in the response received 06 November 2003. Appropriate correction is required.

Specification

6. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

7. The specification is objected to as documents have been improperly incorporated by reference. A review of the instant disclosure finds numerous patent and non-patent documents identified. At page 282 of the specification the following statement is provided.

25 **All publications and patent documents cited in this application are incorporated by reference in their entirety for all purposes to the same extent as if each individual publication or patent document were so individually denoted.**

Such catchall phrase does not properly identify why each of the documents was being incorporated in the original disclosure at the time of filing, and where in each of those documents the incorporated material is to be found. As set forth in *Advanced Display Systems Inc. v. Kent State University* (Fed. Cir. 2000) 54 USPQ2d at 1679:

Incorporation by reference provides a method for integrating material from various documents into a host document--a patent or printed publication in an anticipation determination--by citing such material in a manner that makes it clear that the material is effectively part of the host document as if it were explicitly contained therein. *See General Elec. Co. v. Brenner*, 407 F.2d 1258, 1261-62, 159 USPQ 335, 337 (D.C. Cir. 1968); *In re Lund*, 376 F.2d 982, 989, 153 USPQ 625, 631 (CCPA 1967). **To incorporate material by reference, the host document must identify with detailed particularity what specific material it incorporates and clearly indicate where that material is found in the various documents.** *See In re Seversky*, 474 F.2d 671, 674, 177 USPQ 144, 146 (CCPA 1973) (providing that incorporation by reference requires a statement "clearly identifying the subject matter which is incorporated and where it is to be found"); *In re Saunders*, 444 F.2d 599, 602-02, 170 USPQ 213, 216-17 (CPA 1971) (reasoning that a rejection or anticipation is appropriate only if one reference "expressly

Art Unit: 1634

incorporates a particular part” of another reference); *National Latex Prods. Co. v. Sun Rubber Co.*, 274 F.2d 224, 230, 123 USPQ 279, 283 (6th Cir. 1959) (requiring a specific reference to material in an earlier application in order to have that material considered a part of a later application); *cf. Lund*, 376 F.2d at 989, 13 USPQ at 631 (holding that **a one sentence reference to an abandoned application is not sufficient to incorporate from the abandoned application into a new application**). (Emphasis added.)

8. Accordingly, and in the absence of convincing evidence to the contrary, the cited documents have been considered without effect towards satisfaction of the enablement and written description requirements under 35 USC 112, first paragraph.

Double Patenting

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claims 75-78, 83-86, and 91-94 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 of U.S. Patent No. 6,475,789. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims encompass mammalian cells that comprise a nucleic acid that encodes a fragment of a protein. For purposes of examination, the “fragment” of the protein has been interpreted as being as small as a single amino acid. Additionally, the

Art Unit: 1634

“fragment” may be found embedded within any protein encoded by nucleic acid found within the cell.

11. Claims 75-78, 83-86, and 91-94 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 3-10 of U.S. Patent No. 6,261,836. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims encompass nucleic acid fragments and cells that comprise said nucleic acid that encodes a fragment of a protein. For purposes of examination, the “fragment” of the protein has been interpreted as being as small as a single amino acid. Additionally, the “fragment” may be found embedded within any protein encoded by nucleic acid found within the cell.

12. Claims 75-78, 83-86, and 91-94 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,093,809. Although the conflicting claims are not identical, they are not patentably distinct from each other because the nucleic acid, and cells that comprise the nucleic acid of the instant application fairly encompass polynucleotide “variant or fragment” of claim 1 of the ‘809 patent.

Claim Rejections - 35 USC § 112

13. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 75-78, 83-86, and 91-94 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which

Art Unit: 1634

was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Attention is directed to the decision of *Vas-Cath Inc. v. Mahurkar* 19 USPQ2d 1111 (CAFC, 1991):

This court in *Wilder* (and the CCPA before it) clearly recognized, and we hereby reaffirm, that 35 USC 112, first paragraph, requires a “written description of the invention” which is separate and distinct from the enablement requirement. The purpose of the “written description” requirement is broader than to merely explain how to “make and use”; the “applicant must also convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the “written description” inquiry, *whatever is now claimed*.

14. Claims 75-78, 83-86, and 91-94 fairly encompass vast numbers of nucleic acid sequences, and cells that in turn are to encompass said vast numbers of nucleic acid sequences. As presently worded, the nucleic acids can be simply a “variant” or a “fragment: of an identified polynucleotide. No limitation has been placed on the degree of variability, or on the size of the fragment. Indeed, the “fragment” can seeming be as small as a single triplet, or codon, that would encode a single amino acid. Additionally, the claims fairly encompass variants that lack any activity. A review of the disclosure fails to find an adequate written description of the vast numbers of polynucleotides encompassed by the claims, and their associated cells. Additionally, the specification has not been found to provide an adequate written description of those polynucleotides that would encode a fragment or variant that would in fact be useful. The limited disclosure provided does not reasonably suggest that applicant was in possession of the genus of polynucleotides and cells encompassed by the claims. In support of this position,

Art Unit: 1634

attention is directed to the decision in *In re Shokal*, 113 USPQ 283 (CCPA 1957) wherein is stated:

It appears to be well settled that a single species can rarely, if ever, afford sufficient support for a generic claim. In re Soll, 25 C.C.P.A. (Patents) 1309, 97 F.2d 623, 38 USPQ 189; In re Wahlforss et al., 28 C.C.P.A. (Patents) 867, 117 F.2d 270, 48 USPQ 397. The decisions do not however fix any definite number of species which will establish completion of a generic invention and it seems evident therefrom that such number will vary, depending on the circumstances of particular cases. Thus, in the case of small genus such as the halogens, consisting of four species, a reduction to practice of three, or perhaps even two, might serve to complete the generic invention, while in the case of a genus comprising hundreds of species, a considerably larger number of reductions to practice would probably be necessary.

We are of the opinion that a genus containing such a large number of species cannot properly be identified by the mere recitation or reduction to practice of four or five of them. As was pointed out by the examiner, four species might be held to support a genus, if such genus is disclosed in clear language; but where those species must be relied on not only to illustrate the genus but to define what it is, the situation is otherwise.

15. For the above reasons and in the absence of convincing evidence to the contrary, claims 75-78, 83-86, and 91-94 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

Claim Rejections - 35 USC § 101

16. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

17. Claims 75-78, 83-86, and 91-94 are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility.

18. For purposes of examination, the claims have been interpreted as encompassing polynucleotides that encode “fragments” and “variants” of a telomerase reverse transcriptase protein whereby said protein is void of any activity. The only utility identified for the nucleic acid is for it to encode said telomerase reverse transcriptase protein, however, if the protein has no utility, the nucleic acid that encodes same also lacks utility. Applicant is urged to consider narrowing the claims’ scope such that the variant and fragments so encoded by the claimed polynucleotide do in fact possess this activity, and thereby impart utility to the polynucleotide.

Claim Rejections - 35 USC § 102

19. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

20. Claims 75-78, 83-86, and 91-94 are rejected under 35 U.S.C. 102(b) as being anticipated by Rhyu (*Journal of the National Cancer Society*, June 21, 1995, vol. 87, No. 12).

21. For purposes of examination, the claimed polynucleotide and cells claimed instantly have been interpreted as encompassing any polynucleotide that encodes virtually any telomerase reverse transcriptase protein, as well as any polynucleotide that encodes even a single amino acid found within any telomerase reverse transcriptase protein. Such breadth of scope is inferred from the usage of “variant” and “fragment,” where the “variant” can be any variant, and the fragment can be of any size, and have any degree of similarity to the parent polynucleotide, including zero similarity.

Art Unit: 1634

22. Rhyu, page 887, left column, discloses the cloning of human telomerase, and that telomerase activity has been found in cancer cells. The aspect of human telomerase having been cloned meets the limitation of an isolated polynucleotide, and that it encodes a variant or fragment of a telomerase. The polynucleotide so cloned is considered to have as an inherent property at least one codon that encodes at least one amino acid found in a telomerase reverse transcriptase protein.

Conclusion

23. This is a continuation of applicant's earlier Application No. 08/974,549. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

24. A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

25. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is (703) 308-3978.

The examiner can normally be reached on 6:30 a.m. to 5 p.m., Monday through Thursday.

26. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (703) 308-1119. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

27. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



Bradley L. Sisson
Primary Examiner
Art Unit 1634

BLS
November 15, 2003